

REMARKS

I. Explanation of amendments

The specification has been amended to spell out the first instance of use of the terms "SDS-PAGE," "HPLC," "PCR," and "RACE" as suggested by the Examiner. Claim 50 has been amended to remove recitation of the term MLA.

Claim 49 has been amended to more clearly define the derivation of the term "a fragment" in terms of the functional limitation of having "cytotoxic and/or immunostimulatory activity." Support for this amendment can be found in the specification as originally filed at, for example, page 1, third paragraph, and page 2, second paragraph.

Claims 50, 52, and 53 have been canceled in view of the amendment to claim 54. Claim 54 has been amended to include the sequences previously claimed in claims 50, 52, and 53.

Claim 51 has been amended to add the functional limitation of "cytotoxic and/or immunostimulatory activity." Support for this amendment can be found in the specification as originally filed at, for example, page 1, third paragraph, and page 2, second paragraph.

Claim 78 has been amended to delete the reference to fragments.

Claim 80 has been amended to replace the term "comprising" with the term "consisting of" as suggested by the Examiner.

II. The rejection of claims 49-54 and 78-80 under 35 U.S.C. §112, second paragraph, should be withdrawn.

The Examiner rejected claim 49 and dependent claims therefrom for the recitation of the phrase "or a fragment thereof" alleging that the recitation of the phrase is unclear with respect to the derivation of said fragment. In response, claim 49 has been amended to more clearly define that the fragment may be a fragment of the sequence of SEQ ID NO: 1 or a fragment of the sequence of SEQ ID NO: 40.

The Examiner rejected claim 78 for the recitation of the phrase "and/or." In response, Applicants have amended claim 78 to delete the phrase "and/or a fragment thereof."

The Examiner rejected claim 80 for containing an inappropriate Markush-type wording with respect to the term "comprising." In response, Applicants have replaced the term "comprising" with the term "consisting" as suggested by the Examiner.

In view of the aforementioned amendments and remarks, Applicants respectfully request withdrawal of the rejection of claims 49-54 and 78-80 under 35 U.S.C. §112, second paragraph.

III. The rejection of claims 49-54 and 78-80 under 35 U.S.C. §112, first paragraph, should be withdrawn.

The Examiner rejected claims 49-54 and 78-80 under 35 U.S.C. 112, first paragraph, "...because the specification, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." Specifically, the Examiner alleges that the Applicants have not described any structural variants or fragments of the full-length sequences of SEQ ID NOs: 1, 4, 40 and 41. The Examiner further alleges that the specification does not provide experimental evidence of an animal model or working examples providing evidence of the efficacy of the claimed pharmaceutical compositions. The Examiner also states that the "Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, the first paragraph "Written Description" Requirement make clear that the written description requirement for a claimed invention may be satisfied through sufficient description of a representative example...by functional characteristics coupled with a known or disclosed correlation between function or structure..."

First, the applicants point out that claim 78 has been amended to delete the phrase "and/or a fragment thereof." Second, claims 49 and 51 have been amended to limit the claimed fragments to those which exhibit a specific biological function: a cytotoxic and/or immunostimulatory activity. Further, the polypeptides or polypeptide fragments of claims 49-54 and 78-80 are limited to specific amino acid sequences or (i.e., SEQ ID NOs) or a fragment that comprises a specific amino acid at a specified position (i.e., a phenylalanine at position 533/544). Thus, the combination of the aforementioned structural limitations with the functional limitation of "cytotoxic and/or immunostimulatory activity" sufficiently describes the claimed polypeptides and fragments thereof. Accordingly, the polypeptides and

- fragments recited in the claims are defined by a combination of structural and functional features which can easily be identified by a person of ordinary skill in the art. In view of the foregoing amendments and remarks, Applicants respectfully request withdrawal of the rejection of claims 49-54 and 78-80 under 35 U.S.C. §112, first paragraph.

IV. The rejection of claims 49-51 and 78-80 under 35 U.S.C. §102(b) and §102(e), should be withdrawn.

The Examiner rejected claims 49-51 for allegedly being anticipated by Soler, M. H. *et al.* (*FEBS Lett.* (1996) 399, 153-157) ("Soler *et al.*") and Sweeney, R. A. P. *et al.* (*J. Mol. Biol.* (1993) 234, 1279-1281) ("Sweeney *et al.*") under 35 U.S.C. §102(b). The Examiner states that Soler *et al.* teach the amino acid sequence comprising amino acids 1-62 of SEQ ID NOs: 1, 2, and 40 of the instant application and that the language of claims 49-51 allegedly is unclear with respect to fragment sequences. The Examiner also states that Sweeney *et al.* teach the A chain and B chain of mistletoe lectin polypeptides which are the same molecules of the claimed invention. Additionally, the Examiner rejected claims 49-51 and 78-80 under 35 U.S.C. §102(e) as being anticipated by Lentzen, H. *et al.* (U.S. Patent No. 6,271,368) ("the '368 patent") since the '368 patent allegedly teaches a polypeptide sequence that reads on SEQ ID NOs: 1, 2, and 40 of the instant application.

In response, Applicants have amended claim 49 to insert the limitation "...wherein said fragment comprises a phenylalanine at position 533 of SEQ ID NO:1 and exhibits cytotoxic and/or immunostimulatory activity..." Likewise, a similar limitation was inserted with respect to a fragment for SEQ ID NO 40 in claim 49. As such, the fragments described in claim 49 includes MLB chain sequences. Applicants submit that the prior art only teaches an amino acid sequence of the MLA chain. Accordingly, the prior art is silent with respect to fragments which comprise a phenylalanine at position 533 of SEQ ID NO:1 or a phenylalanine at position 534 of SEQ ID NO:1 and exhibits cytotoxic and/or immunostimulatory activity. Thus, the instant amendments render moot the Examiner's assertion that pending claims of the instant application are anticipated by the prior art and Applicants respectfully request that the rejection of claims 49-51 and 78-80 under 35 U.S.C. §102(b) and §102(e) be withdrawn.

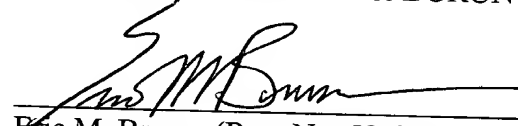
CONCLUSION

Applicants respectfully requests entry of the foregoing amendment, withdrawal of all objections and rejections, and allowance of all of the pending claims in view of the foregoing remarks. The present amendment includes no new matter.

Respectfully submitted,

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By



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